

REMARKS

Applicant's attorney is appreciative of the interview granted by Examiners Duffy and Stone on October 15, 2009, with the attendance of Applicant's French representatives Gerard Portal and Frederic Portal. At that interview, the cited reference was discussed in detail, and arguments were presented as to the distinctions between the invention and the reference.

Amendments to the Specification:

Amendments to the specification have been made to correct several obvious errors.

On page 4, line 24, it is apparent that 'imidiazole" should correctly be - imidazole--.

Also, as outlined at the interview, the passage in the specification on page 6, lines 11-12 must be canceled, since it is apparent that the statement that "the oxidised glycerides content of the compositions of the invention is in general between 7 and 15% by weight" is apparently erroneous. Indeed, the specification mentions on page 4, lines 8 to 14, that the essential constituents are "peroxidised lipids and silica dispersed in said peroxidised lipids at a content greater than or equal to 0.5% by weight and less than 4% by weight," which implies a main or major part of the composition is peroxidised lipids, confirmed by the fact that Example 1 relates to a buccal spray composition wherein the peroxidized lipids are present in an amount of about 94%.

Amendments to the Claims:

New Claims 51-63 have now been added to the application.

New Claims 51 (dependent) and 53 (independent) are directed to the claimed composition, recited as being "non-aqueous." The non-aqueous nature of this composition is clear from the example of the present application, in which no water is present, and can further be seen from the statement that

the essential components are the oxidized glycerol triesters and silicon dioxide, the other constituents being essentially food flavors, on page 3 line 33 to page 4, line 2.

Claim 52 is directed to a combination of the pharmaceutical composition of the invention with a flask comprising a pump spray device, as disclosed in the present specification at page 8, lines 4-9.

Claim 54 is a new independent claim directed to the pharmaceutical composition "consisting essentially of" the peroxidized lipids, the silica, and optionally, flavoring. Such a composition is supported by the example of the present specification.

Claims 55 to 62, dependent on claim 53, have been added to cover the possible further constituents compatible with buccal use, as recited on page 4, lines 21 to 35 of the specification.

Finally, new independent claim 63 has been added to specifically cover Example 1.

With these amendments, no new matter has been added.

Rejection of the Claims:

Claims 27-29 and 31-39 have been rejected under 35 USC 103(a) over Desjonqueres, based upon a translation provided by the United States Patent and Trademark Office.

As discussed at the interview, Applicant believes that a portion of this reference has not been properly translated, and that the last sentence on page 4 of translation should end with the phrase "an oily gel based on colloidal silica."

In order to support this interpretation, Applicant submits herewith a verified translation of paragraphs [0016], [0017], and [0031], and claims 9-10 of EP 1077061.

However, it is believed that the Applicant and the Examiners have both interpreted this term in the same manner, as disclosing a gel containing peroxidized lipids and enough

silica to form a gel, in particular 7 to 9% by weight in the examples. Applicant submits that this composition is clearly distinguished from the invention, in which the peroxidized lipids are combined with silica in amount of less than 4%.

The Office action points out that Desjonquieres also discloses the compositions in the form of an oil-in-water emulsion, a water-in-oil emulsion, a cream, an ointment or a milk. However, Applicant notes that the only specific example provided in this reference is a gel, and only a gel would need to contain silica, as the colloidal silica used is a gel-forming material. As to the other forms disclosed, an ointment would also not be a sprayable material, and would likely contain some ointment forming adjuvant other than silica.

As to the emulsions, the emulsions would not be satisfactory according to the invention since both the oil-in-water emulsion and the water-in-oil emulsion necessarily contain water, which, as explained at the interview, makes the composition unsatisfactory for the purposes of the invention.

The meaning of the term "milk" is unclear, since this term is normally used to represent any material which resembles a milk. Since a "milk" is often an emulsion, a milk is thought to be unsuitable for the sprayable compositions of the invention.

It is further noted that the comparative examples on pages 12 through 14 of the translation of EP 1077061 both contain an "aqueous excipient."

Accordingly, for the purposes of the Desjonquieres reference, to provide mechanical protection for wounds in the oral cavity, a gel would clearly be the most advantageous form of the product, and there is no reason why one of ordinary skill in the art would add silica to any product which is not in the form of a gel.

The Office action further points out that Desjonqueres discloses compositions containing 2 to 99% of peroxidized lipids, and alleges that in the case of the 99% lipid composition, the remaining 1% would be silica. Applicant disagrees, as the examples given by Desjonqueres all contain small amounts of flavorings, which are highly desirable in composition to be applied to the oral cavity. Once again, there is no reason for using colloidal silica in these compositions, except to form a gel.

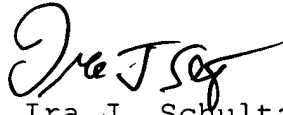
As discussed during the interview, the claimed composition is a composition for treating xerostomia, in the form of a lubricant oil of viscosity sufficiently low to be sprayed onto the surfaces of the mouth and throat. The composition is very effective for its purpose, as described in the two exhibits attached hereto, Exhibit A being *Journal of Clinical Psychopharmacology*, Volume 27, No. 5, October 2007, pages 437-443, and Exhibit B being *Drugs & Aging* 2007, Volume 24, No. 11, pages 957-965. There is nothing in the Desjonqueres reference which discloses or suggests that a composition containing peroxidized lipids and silica, in a lesser quantity than the quantity of silica necessary for forming a gel, would be effective for treating an entirely different problem.

Withdrawal of this rejection is requested.

As noted at the interview, in the event that claims are found to be allowable, Applicant requests rejoinder of method claims of a similar scope.

In view of the foregoing amendments and remarks, Applicant submits that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ira J. Schultz". The signature is fluid and cursive, with the first name "Ira" being more prominent.

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